Proposed Specific Regulatory Level Chemical Causing Cancer: Glyphosate

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To: Barajas-Ochoa, Esther@OEHHA
Subject: Glyphosate NSRL
Date: Tuesday, June 20, 2017 12:31:02 PM

VIA EMAIL: Esther.barajas-ochoa@oehha.ca.gov

June 20, 2017

Ms. Esther Barajas-Ochoa
Regulations Coordinator
Office of Environmental Health Hazard Assessment
PO Box 4010 MS-12B
1001 I Street
Sacramento, CA 95812

Re: Notice of Proposed Rulemaking: Amendment to Section 25705,Specific Regulatory Levels Posing No Significant Risk: Glyphosate

Dear Ms. Esther Barajas-Ochoa,

I am writing in opposition to the proposed NSRL of 1100 micrograms per day for glyphosate. This proposed level does not take into account the following:

1. Glyphosate is an endocrine disruptor.
Here is a link to the PAN monograph on glyphosate and an excerpt from their publication.
http://pan-international.org/wp-content/uploads/Glyphosate-monograph.pdf
Endocrine Disruption
A number of studies have demonstrated that both glyphosate and the Roundup formulation disrupt oestrogen, androgen, and other steroidogenic pathways, and cause the growth of human breast cancer cells.
One study summarises these effects occurring at doses substantially lower than those used in agriculture, or permitted as residues: at 0.5 mg/kg (40 times lower than levels permitted in soybeans in the US) they were anti-androgenic; at 2 mg/kg they were anti-oestrogenic; at 1 mg/ kg they disrupted the enzyme aromatase; at 5 mg/kg they damaged DNA, and at 10 mg/ kg they were cytotoxic. These effects can result in adverse effects in sexual and other cell differentiation, bone metabolism, liver metabolism, reproduction, development and behaviour, and hormone-dependent diseases such as breast and prostate cancer (Gasnier et al 2009).
In vivo experiments in rats show that low levels of glyphosate-based herbicides disrupt the production of testosterone, oestradiol and other steroid hormones, down-regulate the expression of oestrogen progesterone receptors, induce the aromatase activity and protein levels in the testis and cause abnormal sperm morphology.
The implications of the endocrine-disrupting effects can be profound and far-reaching, involving a range of developmental impacts including sexual and other cell differentiation, bone metabolism, liver metabolism, lipid metabolism, reproduction, pregnancy, growth, brain and organ development, cognition, behaviour, and endocrine-related diseases such as breast, testicular and prostate cancer, neurodegenerative and metabolic disorders (diabetes, obesity).

2. Endocrine disrupting chemicals (EDCs) do not follow the classic 'the dose equals the poison' linear graph of toxicity.
EDC's can have nonmonotonic dose responses and low dose effects. The toxicological profile developed by your toxicologists use a linear dose/response graph and is outmoded. See the paper "Hormones and endocrine-disrupting chemicals: low dose effects and nonmonotonic dose responses" by Vandenberg, Colburn, Hayes, et al published in the Endocrine Rev. Published June 2012.

Further, in a position statement published by the Endocrine Society in June 2009, the Society states: “EDC Effects Are Seen At Low Levels of Exposure. Current EDC policy relies largely on data produced from toxicological studies examining the effects of high doses of chemicals. A substance must show adverse effects that increase proportionally with dose in order to be considered dangerous by classical toxicological standards. However, many EDC effects occur at low doses even when high dose effects are not apparent. In fact, increasing amounts of hormone or hormone mimic can squelch a measured adverse effect by over whelming or down-regulating the endocrine system’s ability to respond. In this circumstance, an effect seen at low levels of exposure would not be observed at high levels of exposure. By excluding low-dose studies from policy considerations, the regulatory community may not be accounting for harmful EDC actions that exhibit hormone-like dose-response profiles.”

3. Although the EPA has tested glyphosate and declared that it is not an endocrine disrupting chemical, the Endocrine Society, a professional medical organization, published a position statement in June 2009 that states; “ The EPA has worked for more than 10 years to develop a formal system of screens and tests that would be used to identify potential EDCs in the environment. This Endocrine Disruptors Screening Program (EDSP) has yet to be finalized, but recent basic and clinical research into EDCs has provided significant new information about the mechanisms of EDCs on human health that could require modifications to the plan. Thus, there is concern that this plan, if implemented in its current form, will already be outdated”. Endocrine Society Second Position Paper, 2009
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4702495/

4. Glyphosate is never used alone. It is always used in formulations that include inerts and adjuvants. The inerts and adjuvants have never been tested by the EPA for synergistic effects nor have toxicological studies been done on the complete formulations by the EPA. Once the patents expired on the glyphosate formulations, independent researchers have found that the complete formulations can have toxicities ranging from 100 to 1000 times more toxicity than just glyphosate alone. This research questions the definition of the NSRL for glyphosate, since the NSRL is calculated based on toxicity testing of only the active ingredient, glyphosate.

5. The proposed NSRL is based on an adult weighing 70 kg. This completely excludes the effects on children and fetuses. Children and developing fetuses have ‘windows of development’ where they are particularly vulnerable to the effects of EDCs or other chemicals. To exclude an assessment of the vulnerable in our society is to develop policies that fail to protect them. The EPA has recently stated that children can be up to 65 times more vulnerable to chemicals than adults. Our children are already being born pre-polluted. A study funded by the Environmental Working Group (EWG) and Commonweal tested for 400 chemicals in the umbilical cord blood of 10 newborns selected at random. 287 chemicals were found. Synergistic effects between pre-polluted babies and glyphosate are impossible to determine. How can a ‘daily intake of a chemical to enter the body to pose a lifetime risk of cancer of 1 in 100,000’ be calculated with pre-polluted babies?

6. The NSRL currently proposed is based on a two year diet study of mice and their subsequent carcinogenicity. This fails to account for the potential for transgenerational epigenetic effects of EDCs and pesticides in humans. The classic case of EDCs was the drug DES, given to pregnant women to stop miscarriages. Their female offspring had cases of a rare cancer type, infertility and the grandchildren were also affected by health issues. Studies done on DDT and atrazine, other EDCs, have demonstrated similar patterns of transgenerational epigenetic effects. Based on this knowledge, it would seem that an appropriate study to determine the NSLR of glyphosate should involve mice studies for three generations.

7. The NSRL currently proposed does not take into account the bioaccumulation of glyphosate in animals and humans. According to a study done by Monica Kruger “Chronically ill people had higher levels of glyphosate in their urine than did healthy people”.

8. The NSRL fails to take into account that glyphosate is entering humans and animals in

multiple ways. The USGS has found glyphosate in water and in the rain cycle. Animal studies have found that glyphosate accumulates in meat. Farmers are using glyphosate formulations both as a pre-emergent weed control application and as a dessicant right before harvest. The USDA allows glyphosate on over 160 different crops. How will the NSRL be applied in real life? Will there be an average exposure from the daily diet and the contents of the water and rain? What about agricultural workers who are exposed on the job? The FDA has never done extensive testing of our agricultural products for the residues of glyphosate. What will you use to determine the amounts that humans are exposed to on a daily basis?

9. There has been a drastic decline in the health levels of the American population since glyphosate was approved for use. A study done by Dr. Nancy Swanson, PhD, shows unusual correlations between diseases that have increased and the amount of glyphosate applied. While correlation does not equal causation, the number of correlations is astonishing.

In closing, the science shows that the only safe level of exposure to glyphosate is no exposure. I urge you to follow the science and ban glyphosate in all of its formulations as a public health hazard.

Respectfully submitted,

Mary M. Fraser
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